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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,766	03/03/2004	Michelle M. Hanna	2072.0010008/LBB/SJE	4955

26111 7590 11/01/2006

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,766	HANNA, MICHELLE M.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *136-173* is/are pending in the application.

4a) Of the above claim(s) *138,143,157-161 and 163-170* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *136,137,139-142,144-156,162 and 171-173* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/04 & 12/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 136-163 and 171-173, species (a)(ii), and species, DNA as being the target specific linker, in the reply filed on September 25, 2006 is acknowledged. All together, the claims to which the elected invention embraces are 136, 137, 139-142, 144-156, 162, and 171-173

The traversal is on the ground(s) that the invention defined by Group II includes all limitations of the invention defined by Group I (by way of its dependency on claim 136), but further requires the coupling of the molecule to a solid phase and thus are not divergent in subject matter (page 3, 1st paragraph, Response). Applicants also contend that the claimed molecules are APC (abortive promoter cassette) and that the inventions defined by Groups I and II both are drawn to APC, and thus "structurally similar." (page 3, 1st paragraph, 6th line, Response).

Applicants also argue that even if assuming that the claims are unrelated, a requirement for restriction is proper only if a search and examination of all the claims would impose a serious burden on the Examiner (page 3, 2nd paragraph, Response).

Applicants base their arguments on the fact that the common structure feature of the APC in the claims necessarily entails a coextensive search, stating that according to the USPTO classification descriptions, class 536, subclass 24.3 "cross-references" the class and subclass description of Group II, 435, subclass 6. (page 3, bottom paragraph to page 4, 1st paragraph, Response).

Applicants' arguments are not found persuasive.

Initially, Applicants' arguments drawn to the USPTO classification description cross referencing class 536, subclass 24.3 to class 436, subclass 6, is not found persuasive.

Were Applicants' arguments to be found true, claims drawn to an isolated nucleic acid should be examined together with all methods of using said nucleic acid, such as expressing a protein, detecting any and all kinds of diseases based on hybridization, any and all kinds of amplification methods using said nucleic acid, any and all kinds of therapy methods using the isolated nucleic acid, as all methods drawn to nucleic acid manipulation employ the nucleic acids classified in class 536, subclass 24.3.

Class 436, subclass 6 is a large class encompassing any assays involving nucleic acids and thus for one to examine a nucleic acid of class 536, subclass 24.3 with all methods encompassed by class 436, subclass 6, would create an enormous search and examination burden on the Office.

Lastly, Applicants' arguments drawn to the inventions defined by Groups I and II are found persuasive, in-part. Applicants are advised to leave the claims pending as being withdrawn species, until the independent claims to which the withdrawn claims are dependent from are allowable, and their scope also commensurate with the allowable independent claims, whereupon at the time of allowance, said withdrawn claims will be rejoined.

With respect to Applicants arguments drawn to the election of species requirement, said arguments are not found persuasive for the following reasons.

Applicants contend that the restriction to one of three species of the claimed APCs (of claim 136) is traversed under the basis that the members are of the Markush group and since the members are so "few" in number or so closely related that a search and examination of the entire claim can be made without serious burden (page 4, bottom paragraph, Response).

This contention is not found persuasive because the claims are drawn to a product, whereupon products are examined by its structural elements.

While Applicants may claim that the product is an APC (abortive promoter cassette), any product comprising the structural elements, which may or may not be an APC would anticipate the invention as claimed.

Hence, a search governing a single-stranded oligonucleotide sequence comprising self-complementary sequences would not necessarily return all of the necessary results for a double-stranded oligonucleotides having a bubble region, as well as return all of the necessary results for double-stranded oligonucleotides not required to have bubble region, but that which forms a transcription complex in the presence of an RNA polymerase.

Clearly, the searches required for each of the members of the Markush are not structurally related as Applicants contend, necessitating searches which would result in a search burden.

Applicants also contend that the search of all types of target specific linker, analogously would not pose a serious burden. Applicants' arguments are duly noted, but it is respectfully submitted that the requirement is a species requirement. Upon finding that the elected species is free of prior art, the examination will proceed to the next species. Applicants are advised that if an arbitrary number of species can be selected for the sake of arguing undue search burden, then any number of species can arguably asserted to not pose serious search burden. The restriction requirement clearly set forth that the species were patentably distinct species, to which Applicants do not dispute. In addition, a molecule comprising a DNA linker sequence would structurally be different from the same molecule comprising: RNA, chemically reactive group, amine reactive group, antibody, protein, enzyme, etc. For the Office to formulate multiple anticipatory and/or obviousness rejections for each of the species would clearly result in a serious search and examination burden.

For the above reasons, Applicants' arguments are not found persuasive and the requirement is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 138, 143, 157-161, and 163-170 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 25, 2006.

Preliminary Remark

Claims 136, 137, 139-142, 144-156, 162, and 171-173 are under prosecution herein.

Information Disclosure Statement

The IDS received on March 3, 2004 and December 20, 2004 are acknowledged.

The signed copies of their PTO-1449s are enclosed herewith.

Drawings

The drawings received on March 3, 2004 are acceptable.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 136, 137, 139-142, 144-156, 162, and 171-173 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 136 is indefinite because a proper Markush group has not been identified.

Specifically, claim sets forth a Markush group of three members, but does not recite a proper conjunction after the member (b) and (c), rendering the claim confusing how many members make up a Markush group. For the purpose of prosecution, the conjunction "and" has been assumed between the member (b) and the member (c).

Claims 137, 139-141, 149, 150, 151-156, 162, and 171-173 are indefinite by way of their dependency on claim 136.

Claims 139-141 are indefinite because it is unclear what is meant by the limitation, "further comprising a promoter," because the instant specification does not specifically define what is considered to be a promoter. Based on the broadest reasonable interpretation of the claims, a promoter is structure which allows transcription to take place. This interpretation has been assumed for the purpose of prosecution.

Claim 142 is indefinite because the product is defined by elements (c), (d), (e), (f), and (g), but fails to mention the elements (a) and (b), rendering the claim confusing what elements are missing from the claim.

Claim 142 reiterates the element, "a target-specific linker sequence attached to either the 3' or 5' end of one strand" twice (see elements (c) and (g)). It is unclear which strand the "one strand" is referring to in view of this reiteration. For the purpose of prosecution, the second iteration is assumed to be omitted.

Claims 144-148 are indefinite by way of their dependency on claim 142.

Claims 149 and 150 are indefinite for reciting the term, "said nucleic acid."

There is insufficient antecedent basis for this limitation in the claims. No reasonable interpretation could be made for these claims for the purpose of prosecution.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims ???? are rejected under 35 U.S.C. 102(b) as being anticipated by Munroe et al. (U.S. Patent No. 5,597,694, issued January 28, 1997).

The instant rejection is based on the fact that the claims are drawn to a product. So long as the prior art disclosure meets all of the limitations set forth in the product claims, said claims are anticipated and discovery of new property or use of previously known composition, even if unobvious from prior art, cannot impart patentability to claims to known composition (*In re Spada*, 15 USPQ2d 1655, 911 F2d 705, August 10, 1990).

Munroe et al. disclose a molecule comprising a two partially complementary upper and lower oligonucleotides that form a single-stranded transcription bubble region comprising a defined site (see Figure 1, "Bubble Oligos"; column 2, lines 52-60) and a linker on at least 3' or 5' end of its strand (bubble complex is specifically ligated to its target sequences which are digested with blunt cutting restriction enzymes, *see* column 2, lines 50-51 and 58), thereby clearly anticipating claims 136 137, 139-142, 171, and 172.

With regard to claims 144 and 146, Munroe et al. disclose that the complementary regions of the bubble complex which flank the single-stranded region, comprise approximately 10 to approximately 50 complementary nucleotides (column 2, lines 53-55).

With regard to claim 145, Munroe et al. disclose that the single-stranded region of the bubble complex comprises approximately 15 to approximately 35 nucleotides (column 2, lines 55-57).

With regard to claims 151-155, the bubble complex is disclosed as being ligated to phage clone (column 2, lines 49), or nucleic acid specific to disease, disorder, or condition such as fragile x syndrome, acute myelocytic leukemia, and solid tumors (column 11, lines 60-67).

Therefore, Munroe et al. anticipate the invention as claimed.

Claims 136, 137, 139-142, 144-147, 151-156, 171, and 171 are rejected under 35 U.S.C. 102(b) as being anticipated by Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2[1]; herein, Daube 2).

Daube 1 discloses a molecule comprising a two partially complementary upper and lower oligonucleotides that form a single-stranded bubble region comprising a defined site (see Figure 1 on page 9540, 1st column) and a linker on at least 3' or 5' end of its strand (by treatment with BamH1 restriction enzyme; see page 9540, 1st column, 2nd paragraph), thereby anticipating claims 136, 137, 139-142, 171, and 172.

With regard to claims 144-146, Daube 1 refers to Daube 2 for the disclosure of the bubble complex structure (page 9540, 1st column, 2nd paragraph).

Daube 2 evidences that the bubble complex of Daube 1 comprises a two partially complementary upper and lower oligonucleotides that form a single-stranded bubble region comprising a defined site (see Figure 1), wherein said bubble complex comprises 16 nucleotides of upper complementary region, followed by 12 nucleotides of single-stranded region, followed by a lower complementary region comprising various restriction enzyme recognition sites (the first one appearing at the 12th nucleotide position; see Figure 1, Sal 1).

With regard to claim 147, the bubble-duplex comprises an overhang generated by digestion with BamH1 restriction enzyme.

With regard to claims 151-156, a target sequence drawn to any of the disorders would inherently comprise a restriction enzyme recognition site, and thus, the bubble construct of Daube 1 would necessarily be specific to such target sequences (i.e., ligate thereto).

Therefore, the invention as claimed is anticipated by Daube 1 as evidenced by Daube 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 136, 137, 139-142, 144-148, 151-156, and 171-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2[1]; herein, Daube 2) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993).

The present rejection is based on an alternative claim interpretation, wherein the limitation imposed by the element, "target-specific linker" is interpreted to mean that the linker sequence is specifically formulated to hybridize to a target sequence (independent from restriction enzyme recognition sites).

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[1] IDS received on December 20, 2004.

Daube 1 discloses a molecule comprising a two partially complementary upper and lower oligonucleotides that form a single-stranded bubble region comprising a defined site (see Figure 1 on page 9540, 1st column) and a linker on at least 3' or 5' end of its strand (by treatment with BamH1 restriction enzyme; see page 9540, 1st column, 2nd paragraph).

Daube 1 refers to Daube 2 for the disclosure of the bubble complex structure (page 9540, 1st column, 2nd paragraph).

Daube 2 evidences that the bubble complex of Daube 1 comprises a two partially complementary upper and lower oligonucleotides that form a single-stranded bubble region comprising a defined site (see Figure 1), wherein said bubble complex comprises 16 nucleotides of upper complementary region, followed by 12 nucleotides of single-stranded region, followed by a lower complementary region comprising various restriction enzyme recognition sites (the first one appearing at the 12th nucleotide position; see Figure 1, Sal 1).

The bubble-duplex comprises an overhang generated by digestion with BamH1 restriction enzyme.

Daube 1 and Daube 2 do not explicitly disclose that the bubble complex comprise a target-specific linker on at least the 3' or the 5' end of one strand of said bubble complex, wherein the target-specific linker comprises a single-stranded overhang region from about 10 to about 25 nucleotides.

Daube 1 and Daube 2 do not explicitly disclose that the target-specific linker is specific to a target DNA, mRNA or sequence specific to disease, disorder, or conditions.

Berninger et al. disclose a well known method of amplifying a desired target sequences by ligating a proto-promoter sequence thereto, wherein the ligation of said proto-promoter sequence

allows the generation of reiterative transcription products of the ligated target sequence (see Figure 1; column 3, lines 31-33)

Berninger et al. explicitly disclose that the proto-promoter sequence comprises a double-stranded region and a single-stranded segment (thus comprises an overhang, see Figure 1; column 3, lines 56-57).

Berninger et al. explicitly disclose that such technique may be used in diagnostic assays.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Daube 1, Daube 2, and Berninger et al., thereby arriving at the claimed invention for the following reasons.

The teachings of Daube 1 and Daube 2 are clear in that the artisans clearly demonstrate that nucleic acid transcription reaction could take place without the actual promoter sequences, but rather facilitated by structure which is recognized by an RNA polymerase (i.e., bubble complex).

Daube 1, in particular, demonstrates that a transcript of desired length and position can be generated via use of RNA trap (Abstract).

Based on such teachings, one of ordinary skill in the art at the time the invention was made would have been motivated to applying the teachings of Daube 1 and Daube 2, for the purposes of generating a bubble complex which is capable of generating multiple transcription products from a desired target sequences in a diagnostic assay.

One of ordinary skill in the art at the time the invention was made would have had a clear expectation of success in arriving at combining the teachings given the fact that Berninger et al. demonstrate the feasibility of ligating a promoter sequence to a target nucleic acid sequence, whereupon RNA polymerase is able to generate multiple transcripts therefrom. Based on such demonstration, one of ordinary skill in the art at the time the invention was made would have not

had any doubt that ligating/hybridizing an end of a promoter construct which is capable of initiating transcription reaction (as clearly demonstrated by Daube 1 and Daube 2), said ligation/hybridization being specific for a desired target nucleic sequence, in a diagnostic assay would have worked.

It should be noted that Daube 1 and Daube 2 already demonstrate that ligation of their bubble complex to a plasmid sequence resulted in the generation of multiple transcript products therefrom.

With regard to the target-linker being specific for various diseases, conditions, or disorders, such would be an obvious target since methods involving amplification reaction are routinely involved in amplifying nucleic acid sequences which are implicated with diseases, conditions, or disorders, such as cancers, pathogens, etc.

For the above reasons, the invention as claimed is *prima facie* obvious over the cited references.

Claim 162 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daube et al. (PNAS, 1994, vol. 91, pages 9539-9543; herein, Daube 1) as evidenced by Daube et al. (Science, 1992, vol. 258, pages 1320-1324; IDS ref# AR2[1]; herein, Daube 2) in view of Berninger et al. (U.S. Patent No. 5,194,370, issued March 16, 1993) as applied to claims 136, 137, 139-142, 144-148, 151-156, and 171-173 above, and further in view of Kim et al. (U.S. Patent No. 5,846,723, issued December 8, 1998).

The teachings of Daube 1, Daube 2, and Berninger et al. have already been discussed above.

None of the immediately discussed artisans explicitly disclose that the linker should be specific for telomerase.

Kim et al. disclose a well known practice for detecting telomerase activities for the purposes of detecting malignant cancers (column 1, lines 34-37).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Daube 1, Daube 2, and Beninger et al., with the teachings of Kim et al., thereby arriving at a molecule comprising a target specific linker for telomerase, because by doing so, one of ordinary skill in the art would have been capable of detecting, diagnosing, or monitoring cancer in a sample. Given the fact that one of ordinary skill in the art would have been motivated to employ the bubble complex of Daube 1 and Daube 2 in view of the teachings of Berninger et al., one of ordinary skill in the art would have had a reasonable expectation of success at designing any target specific linker so long as there was motivation to amplify a target sequence.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 136, 137, 139-142, 144-148, 151-156, 162, 171-173 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-31 and 35-43 of copending Application No. 10/976,240 (herein, '240 application). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims of '240 application is drawn to a narrower species of the generic construct as claimed in the instant application, and thus renders the instant claims obvious in a genus-species reasoning. While claims 23-31 of '240 application recites a generic term, "abortive promoter cassette," in view of the Figures of '240 application referencing an abortive promoter cassette, the constructs are identical to the construct defined in the instant application, and therefore, deemed obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Primary Examiner
Art Unit 1637
10/24/2006

YOUNG J. KIM
PRIMARY EXAMINER

YJK